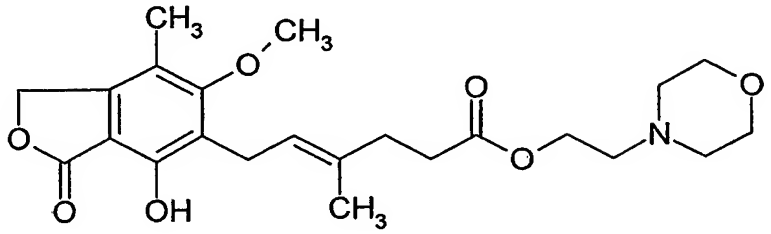
Claims:

1. Process for the purification of mycophenolate mofetil [mycophenolic acid 2-(4-morpholinyl)ethyl ester] of formula I



I

by removing its by-products, whereby a solution or suspension of mycophenolate mofetil is treated with a primary or secondary amine.

2. Process according to claim 1, characterised in that the by-products contain dimers.

3. Process according to claim 1 or 2, characterised in that the primary or secondary amine has the following formula:

- whereby R_1 is hydrogen or Y, and
- whereby X and Y may be identical or different, and X or Y may each be
  a) hydrogen, or
  b) an optionally substituted C_1-C_{12}-alkyl group, which is optionally interrupted by a hetero atom from the series nitrogen, oxygen or sulphur or by an alkylene group, or
  c) an optionally substituted aryl group, or
  d) an optionally basic aromatic heterocycle, or
  e) an optionally substituted saturated or unsaturated aliphatic 3- to 8-membered ring, which may optionally contain hetero atoms from the series nitrogen or oxygen, or
- whereby X with R1 forms an optionally substituted saturated or unsaturated aliphatic 3- to 8-membered ring, which may optionally contain hetero atoms from the series nitrogen or oxygen.

4. Process according to claim 3, characterised in that the substituents are alkyl, carboxyl, alkoxy or hydroxy groups, or aryl groups which optionally contain alkyl, carboxyl, alkoxy or hydroxy groups, or are amino groups, monoalkyl- or monoaryl-amines,

dialkyl- or diaryl-amines, a trialkylammonium or triarylammonium group, a cyclic amine or a basic heterocycle.

5. Process according to claim 4, characterised in that the substituents stem from the groups n-butylamine, ethylendiamine, diaminobutane, diaminopentane, diaminohexane, diaminocyclohexane, or dimethylaminopropylamine, for example 3-N,N-dimethylamino-1-propylamine.

6. Process according to one of claims 1 to 5, characterised in that the primary or secondary amine is soluble in an organic solvent.

7. Process according to claim 6, characterised in that the organic solvent includes a ketone, for example acetone or methyl isobutyl ketone, or a C_1-C_4-alcohol, or a nitrile, for example acetonitrile, or an inert solvent, optionally in the presence of a cosolvent, or mixtures thereof.

8. Process according to claim 7, characterised in that the inert solvent is an acetic acid (C_1-C_4)-alkyl ester or a halogenated hydrocarbon, optionally in the presence of a cosolvent.

9. Process according to claims 7 or 8, characterised in that the inert solvent is ethyl acetate, isopropyl acetate or dichloromethane, optionally in the presence of a co-solvent.

10. Process according to one of claims 7 to 9, characterised in that the cosolvent is an organic amide.

11. Process for the purification of mycophenolate mofetil, characterised in that it comprises the following reaction steps:

a) activation of mycophenolic acid by forming a reactive derivative in an inert solvent,

b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,

c) treating it with a primary or secondary amine, and

d) isolating the mycophenolate mofetil.

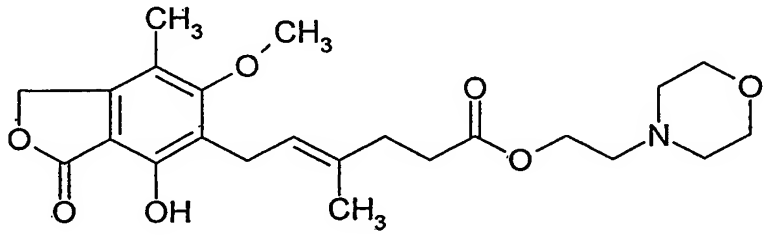
12. Process for the purification of mycophenolate mofetil, which contains by-products, characterised in that it comprises the following reaction steps:
    a) preparing a solution or suspension of mycophenolate mofetil as a free base in an inert solvent,
    b) treating it with a primary or secondary amine, and
    c) isolating the mycophenolate mofetil.

13. Process according to claim 12, characterised in that the by-products contain dimers.

14. Mycophenolate mofetil as the free base with a maximum content of dimers of 0.15% (area percent HPLC).

15. Mycophenolate mofetil as the free base with a content of dimers of 0.15 to 0.03% (area percent HPLC).

16. Process for the production of mycophenolate mofetil [mycophenolic acid 2-(4-morpholinyl)ethyl ester] of formula



whereby a reactive derivative of mycophenolic acid is produced in an inert solvent and is reacted with 4-(2-hydroxyethyl)morpholine, and the resulting mycophenolate mofetil is isolated from the reaction mixture, characterised in that
    I) 4-(2-hydroxyethyl)morpholine is added under controlled conditions to the solution of the reactive derivative of mycophenolic acid, whereby the reaction takes place under acidic reaction conditions, and
    II) isolation of mycophenolate mofetil is effected by forming an acid addition salt and subsequently releasing the free base.

17. Process according to claim 16, characterised in that it contains the following process steps:
    a) activation of mycophenolic acid by forming a reactive derivative

b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,

c) isolating mycophenolate mofetil through the formation of an acid addition salt, and

d) releasing the free base of mycophenolate mofetil from the acid addition salt.

18. Process according to one of claims 11, 16 or 17, characterised in that the reactive derivative of mycophenolic acid is an acid halide.

19. Process according to claim 18, characterised in that the acid halide is an acid chloride.

20. Process according to one of claims 16 to 19, characterised in that the acid addition salt of mycophenolate mofetil is the oxalate or the hydrochloride of mycophenolate mofetil.

21. Process according to one of claims 16 to 20 comprising the following process steps:

a) activation of mycophenolic acid by forming a reactive derivative,

b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,

c) treating the reaction mixture with a primary or secondary amine,

d) isolating mycophenolate mofetil through the formation of an acid addition salt, for example the oxalate, and

e) releasing the free base of mycophenolate mofetil from the acid addition salt.

22. Process for the purification of mycophenolate mofetil, characterised in that it comprises the following reaction steps:

a) preparing a solution or suspension of mycophenolate mofetil as an acid addition salt in an inert solvent,

b) releasing the free base,

c) treating it with a primary or secondary amine, and

d) isolating the mycophenolate mofetil.

23. Process according to claim 22, characterised in that the acid addition salt of mycophenolate mofetil is the oxalate or the hydrochloride of mycophenolate mofetil.

24. Mycophenolate mofetil as the oxalate with a maximum content of dimers of 0.1% (area percent HPLC).

25. Mycophenolate mofetil as the oxalate with a content of dimers of 0.1 to 0.03% (area percent HPLC).